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| 10/500,297      | 06/28/2004  | Rick V. Hay          | 28927.0009          | 2642             |

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| EXAMINER |
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DAVIS, MINH TAM B

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| ART UNIT | PAPER NUMBER |
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1642

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12/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/500,297

Applicant(s)

HAY ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 9, 12-19, 21-25, 31-32, 35-39, 52, 60, 65-66, 70-72, 76, 80, 84, 88, 92, 124-126 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1,6,9,12-19,21-25,31,32,35-39,52,60,65,66,70-72,76,80,84,88,92 and 124-126.

***DETAILED ACTION***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

Applicant cancels claims 4, 7, 45-47, 49-51, 58-59, and adds new claim 126.

Accordingly, claims 1, 6, 9, 12-19, 21-25, 31-32, 35-39, 52, 60, 65-66, 70-72, 76, 80, 84, 88, 92, 124-126 are examined in the instant application.

***Withdrawn Rejection***

The following rejections have been withdrawn: 1) Objection for the use of the abbreviated language "PET" in view of the amendment, 2) 112, second paragraph, in view of the amendment, 112, first paragraph, written description and 112, first paragraph, after review and reconsideration and in view of the amendment, and 102 rejection, in view of the amendment.

***Specification***

The amendment of the specification of 10/30/07 is acknowledged. The specification, however, is still objected to because the abstract is still missing.

***Objection***

Claims 37-39, 92 remain objected to for the use of the abbreviated language “MRI” in claims 37, 92, for reasons already of record in paper of 04/30/07.

The response asserts that the claims have been amended to recite the full names.

The response has been considered but is not found to be persuasive for the following reasons:

.Although claim 19 has been amended, claims 37-39, 92 are not amended.

***Claim Rejections - 35 USC § 112, First Paragraph, Deposit***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 6, 7, 9, 12-19, 21-25, 31-32, 35-39, 45-47, 49-52, 58-60, 65-66, 70-72, 76, 80, 84, 88, 92, 124-125 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement under deposit rule, for reasons already of record in paper of 04/30/07.

In the response, the specification is amended to include the site and the date of the deposition, and record of the deposit under Budapest Treaty is submitted.

The response asserts that the signed applications/statements made by one of the inventors as part of the ATCC deposit process for mAbs Met3 and Met5, along with the ATCC deposit receipts.

The amendment and the submission of the deposit record is acknowledged.

The response has been considered but is not found to be persuasive for the following reasons:

Rejection remains, because “even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990)”. Further, a product could be commercially available but only at a price that effectively eliminates accessibility to those desiring to obtain a sample. See also the final rule entitled “Deposit of Biological Materials for Patent Purposes,” 54 FR 34864, 34875 (August 22, 1989). Applicant’s attention is directed to 37 CFR 1.801-1.809 for further information concerning deposit practice.

It is suggested that Applicant submits a statement, reciting that all restrictions upon public access to the deposits will be irrevocably removed upon the granting of a patent on this application, and that the deposit will be replaced if viable samples cannot be dispensed by the depository.

***New Rejection Based on the Amendment***

***Objection***

1. Claims 12, 17, 60, 65, 66, 70-72, 76, 80, 84, 88, 92 are objected to for the use of the abbreviated language "Met".

2. Claim 32 is objected to, because the amendment is not marked with a line.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 6 is indefinite for the use of the language “substantially”, which is a relative term. The term "substantially " is not defined by the claim, or in the specification, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, it is not clear that outside the variable region, which of the amino acids are of human origin.

This rejection could be obviated, for example, by deleting item b of claim 6.

2. Claim 32 is indefinite for the use of the Trademark in the claim.

MPEP 7.35.01 teaches that where a trademark or trade name is used, “the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name” See *Ex parte Simpson*, 218 USPQ 1020 (Bd.App.1982). In the present case the trade name is used to describe a fluorescer and, accordingly, the description is indefinite.

Claim 32 is also indefinite for the use of the language “a fluorescein derivative”. It is not clear what is a derivative of a fluorescein.

***Claim Rejections - 35 USC § 112, First Paragraph, Scope***

Claim 65 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a kit comprising the antibody of claim 1 for diagnosis of cancer, does not reasonably provide enablement for a kit comprising the antibody of claim 1 for diagnosis of diseases known or suspected to express Met. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. The claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 ( Fed.Circ.1988 ) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The specification discloses that the receptor protein tyrosine kinase (Met) is overexpressed in various cancers (p.2-3). The specification discloses that under normal conditions Met is a keystone molecule, acting on the molecular signaling pathways responsible



for cellular differentiation, motility, proliferation, organogenesis, angiogenesis, and apoptosis (p.2). The specification however does not have any data or objective evidence that diseases other than cancers overexpress Met.

One cannot predict that the claimed antibody could be used successfully for diagnosis of diseases that express Met, because Met is also expressed in normal tissues, as disclosed in the specification, and one cannot predict that Met is overexpressed in diseases other than cancers. It is well known in the art that different diseases have different etiology and characteristics, and that not every gene in a diseased cell has mutation or changes in expression as compared to normal control cells. For example, Stanton, P et al, 1994, Br J Cancer, 70: 427-433 teach that the level of expression of epidermal growth factor receptor (EGFR) cannot be predicted from cell lines or tumors (p.432, second column, last paragraph), and that from ten tumors from which the cell lines are derived, only two of the tumors display elevated levels of EGFR, BICR6 and BICR18 proteins (table V on page 430, and first column, last paragraph of page 430) In other words, not only the level EGFR, BICR6 and BICR18 proteins are the same as normal control in 8 tumors, the rest of other proteins in table V are not different from normal control in all ten tumors. Similarly, Ihle, C et al, 1999, J Steroid Biochem Mol Biol, 68: 189-195, teach that although the level of 5-alpha-reductase-1 is increased in prostate cancer tissue, the level of the isoform 5-alpha-reductase-2 is the same as that of normal prostate (abstract). Abbaszadegan, M R, et al, 1994, Cancer Res, 54: 4676-4679, teach that the level of multidrug resistance-associated protein (MRP) detected in malignant hematopoietic cells is similar to the level found in normal hematopoietic cells (p.4678, second column, last 6 lines of second paragraph).

MPEP 2164.03 teaches that “the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling.”

Given the above unpredictability, and in view of the complex nature of the invention, a lack of sufficient disclosure in the specification, and little is known in the art concerning the claimed invention, it would have been undue experimentation for one of skill in the art to practice the claimed invention, that is commensurate in scope of the claims.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

Application/Control Number:  
10/500,297  
Art Unit: 1642

Page 9

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS  
December 03, 2007

/Larry R. Helms/  
Supervisory Patent Examiner